REMARKS

Claims 54, 56, 60-64, 66, 67, 69, 72, 73 and 76-86 are pending. Claims 54 and 82 have been amended and the following remarks presented.

Claims 54, 56, 60-64, 66, 67, 69, 72, 73 and 77-86 were rejected under 35 USC 103(a) as being unpatentable over Casper et al in view of Fiedler et al and Ladner. The reasons for the rejection were essentially the same as given before. This rejection is respectfully traversed for substantially the same reasons given before, incorporated by reference here, and the following clarifying points.

The examiner has criticized many of the claim recitations as mere methods for making a product or intended use and do not carry any patentable weight. However, many argued claim recitations describe structures within the claimed composition that affect the composition of the claimed composition. These are not mere intended use or preparation methods but directly impact the nucleic acid sequence of the polynucleotide. Should any confusion be present, the claims have been amended to a more conventional form, noting that the polynucleotide composition contains the recited nucleic acid sequences. For example, the term "vector" is more than an intended use for any polynucleotide of any sequence. The term "vector" may be an intended use but it is also a limitation of the sequence of a polynucleotide.

All claims are directed to polynucleotides comprising different portions, each having certain nucleic acid sequences. For example, the claim language "...a nucleic acid sequence promoting expression of said polypeptide in a plant cell or plant..." refers to a composition within the claimed polynucleotide and the composition is defined as that "promoting expression ... in a plant cell or plant". Such a nucleic acid sequence may be a plant promoter. The defining language is not mere intended use because most nucleic acid sequences are not plant promoters. The language is not merely an intended use but a definition of the structure of the nucleic acid sequence, a composition of matter and part of the claimed polynucleotide. Likewise for the other recitations which are structural descriptions in the claim.

Specifically, the examiner criticizes the recitation of expression in plant cells as method for making the product and the polypeptide being capable of inducing an immune response as being intended use. However, not all polynucleotides are expressed in plants but rather only those with

the necessary regulatory regions and structural gene sequences compatible with a plant cell. Likewise, not all polypeptides are capable of inducing an immune response. Only those with certain amino acid sequences will satisfy the recitation and the Examiner is well aware that the polypeptide's amino acid sequence is determined by the nucleic acid sequence of the polynucleotide. Therefore, these types of recitations represent actual functional requirements to the claimed composition.

On page 3 of the rejection mailed July 28, 2004, the examiner states "statements made by the applicant regarding the expression vectors ability to express "at all or in the same fashion are unsubstantiated and are made without objective evidence." However, the abilities of the claimed invention have been shown by experimental results given in the specification. This is not "unsubstantiated". The abilities of the vectors in Fiedler et al are objectively those presented in their journal article. The ability of the vectors used in Fiedler et al to produce transgenic plants rather than replicate transiently in the cytoplasm is also taught by Fiedler et al and the properties of such vectors is also known in the art and discussed in dozens of U.S. Patents.

In the last paragraph on page 3 of the rejection mailed July 28, 2004, the examiner states "the use of randomized linkers was also well known as evidenced by Tang Y et al." However, Tang et al use completely random linkers of 18 amino acids in length. The claims do not recite completely randomized linkers but rather a repeated pattern of degenerate repeated triplet nucleotides, which have certain restrictions as to which nucleotide, may be at each position. For example claims 69 and 78 recites that position 3 of the repeated triplet is deoxythymidine. At least that position is fixed and not random as in Tang et al. Likewise for other positions. Therefore, none of the references applied as well as Tang et al teach a linker having the claimed repeated pattern of degenerate repeated triplet nucleotides.

None of the references disclose or motivate one to make a polynucleotide with "a nucleic acid sequence inducing transient replication ...in the cytoplasm", much less a polynucleotide with this sequence and a sequence for a specific epitopic portion of an immunoglobulins. This feature is claimed in claim 54 and 82 in particular.

None of the references disclose that a plant is capable of producing an immunoglobulin (or the specific antigen portion) that will elicit an immune response in a mammal. This feature is claimed in claims 54, 72, 73 and 82 in particular. The only Fiedler et al produce immunoglobulin

in plants and there was no evidence that such a protein has that capability. From the recombinantly produced immunoglobulins specific antigens made in Casper et al, an adjuvant such as KLH or GM-CSF was used and apparently needed to elicit an immune response. See claim 81 in particular.

None of the references disclose a member of a library of linkers encoded by a polynucleotide having a degenerate repeated triplet nucleotide with the claimed criteria. See claims 66, 67, 77, and 78 in particular.

Claims 54, 56, 60-62, 64, 72, 73, 76 and 81-86 were rejected under 35 USC 102(a) as being anticipated by McCormick et al. This rejection is respectfully traversed.

A declaration from the inventors regarding the contributions of the co-authors in the McCormick et al article was previously provided as Exhibit B to the amendment filed March 31, 2003. As such McCormick et al is not prior art and the rejection should be withdrawn.

Claims 54-64, 72-76 and 81-86 were rejected under 35 USC 101 as being drawn to a naturally occurring polynucleotide, namely the polynucleotide encoding the gene for one of the immunoglobulin chains. Such a naturally occurring polynucleotide would be a chromosome or fragment thereof. This rejection is respectfully traversed.

Several locations in these claims recite structures containing nucleic acid sequences different from a naturally occurring polynucleotide encoding an immunoglobulin chain gene. Claim 54 recites "A" (one) polynucleotide encoding three sequences, 1) the immunoglobulin, 2) "a nucleic acid sequence promoting expression of said polypeptide in a plant cell or plant" and 3) "a nucleic acid sequence inducing transient replication of said polynucleotide in the cytoplasm". A mammalian gene does not naturally occur with a plant promoter. A mammalian gene does not naturally occur with cytoplasmic replication sequences. The claim describes an artificial construct, not a naturally occurring polynucleotide. Claims 61 and 86 require the polynucleotide to encode a polypeptide with at least part of the V_H and at least part of the V_L domains. Naturally occurring polynucleotides encoding the V_H and the V_L domains occur in genes producing separate polypeptides, not a fusion peptide having both domains. Claim 82 recites "A" (one) polynucleotide encoding a nucleic acid sequence for the immunoglobulins and a nucleic acid sequence encoding "a vector capable of transiently replicating in the cytoplasm of and promoting expression of said polypeptide in a plant cell or plant". A polynucleotide encoding a mammalian

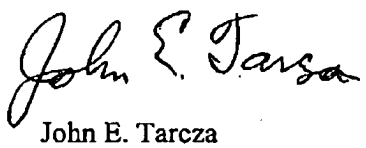
gene in a vector does not occur naturally, nor does a mammalian gene occur with a plant cell promoter naturally, nor does a mammalian gene occur naturally with a sequence for replication in a plant cytoplasm. If this were not enough, claim 82 requires the vector to be a plant virus. An immunoglobulin gene in a plant virus vector is obviously an artificial construct. As for claim 84, an immunoglobulin gene does not naturally express in a plant. As for claim 85, vectors having subgenomic promoters containing an immunoglobulin gene also are artificial constructs. Accordingly, the claimed polynucleotide is not a naturally occurring composition and the rejection should be withdrawn.

CONCLUSIONS

In view of the amendments and comments above, the rejections have been overcome. Reconsideration, withdrawal of the rejections and early indication of allowance are respectfully requested. If any issues remain, the examiner is encouraged to telephone the undersigned.

If needed, applicants petition for an extension of time under the provisions of 37 CFR 1.136(a) for sufficient time to accept this response. The commissioner hereby is authorized to charge payment of any fees under 37 CFR § 1.17, which may become due in connection with the instant application or credit any overpayment to Deposit Account No. 500933.

Respectfully submitted,



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